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challenges to overcome regarding the overall ethics system. Applying same ethics regulations or guidelines from interventional studies may not be the most adequate choice for observational studies.

PHP286

STATE OF THE ART RESEARCH IN AUSTRIA: DEXHELPP - DECISION SUPPORT FOR HEALTH POLICY AND PLANNING: METHODS, MODELS AND TECHNOLOGIES BASED ON EXISTING HEALTH CARE DATA

Zauner G[1], Popper N[1], Breitenecker F[2]
[1]*dwh GmbH, Vienna, Austria,* [2]*Vienna University of Technology, Vienna, Austria*

The Austrian health care system incurs costs of 30 billion/year, the bulk of the costs (77%) are publicly financed. Health policy and decision planning based on research evidence helps to tackle increasing costs. The urgent need for the evaluation of new health technologies, services, infrastructure, as well as for the development of improved technologies for the analysis, planning and control of health systems is met by DEXHELPP. **METHODS:** Today, decision support in health care is usually based on evidence from studies of limited size, but not yet on the analysis of large volumes of routinely collected health care data. *DEXHELPP* is dedicated to filling the gap by combining academic excellence by research partners with professional implementation including knowledge of commercial partner institutions. By doing so special methods for statistical analysis, simulation and visualisation will be implemented as well as new methods for documentation and providing of k-anonymity for used individual data. For this task, existing cooperation schemes provide a firm substantial and conceptual knowledge base. All relevant fundamental technological competencies from academic and applied research are provided by the consortium, coming from universities, competence centres, and R&D SMEs. **RESULTS:** Developed methods will help in (1) analysing the status quo, (2) making reliable prognoses, and (3) evaluating the consequences of interventions. A scientific research server with routine data in order to test developed methods will be run. The project covers all relevant areas within this complex process, from data management via analysis and modelling through to user friendly presentation of results and quality assurance. Some of the most important actual decision-makers in Austria complete the consortium with application-oriented expertise. **CONCLUSIONS:** DEXHELPP focusses on the development on high innovative technological methods. Future focus will lay on building up a network with more stakeholders to integrate those methods in national and international processes.

PHP287

PROPOSED FRAMEWORK FOR PATIENT AND PUBLIC INVOLVEMENT IN THE HTA PROCESS IN IRELAND

Walsh C
Trinity College Dublin, Montenotte, Ireland

The rationale for patient and public involvement (PPI) in the Health Technology Assessment (HTA) process has been widely documented. Engagement of patients or public in the process facilitates a broadening of scope and delineates a role for the patient as an 'expert witness' who has unique insight to living with an illness and the potential benefits/disadvantages (including side effects) that medical technology may offer. Our objective was to explore the concept of practical and meaningful public participation in the HTA process and present a research protocol to propose a PPI framework applicable to the Irish context. A qualitative systematic literature review and concept analysis was used to identify key attributes relating to patient and public involvement. It is proposed that this knowledge will be supplemented through semi-structured interviews of key informants and a review of a purposive sample of HTA agency websites. Researchers, decision makers and policy makers will contribute to development and refinement a framework through a process of deliberation. Capturing the diverging perceptions of key informants will lead to the enhancement of the proposed framework. The role of the publics will be clarified, various levels and methods of PPI further defined. This research will explore the concept of PPI and suggest a study protocol for the development of a framework for PPI in the context of the Irish HTA process.

PHP288

PATIENT ACCESS TO LIFE-SAVING MEDICATION; PREVENTING STOCK-OUTS DUE TO PARALLEL TRADE

Ratcliffe M[1], Mbanya Z[2], Gielen V[1], Sparrowhawk K[1]
[1]*PHMR Associates, London, UK,* [2]*PHMR Associates, Newcastle Upon Tyne, UK*

Manufacturers and suppliers of potentially life-saving drugs must ensure adequate supplies of in-date drug formulations for all markets across Europe. Failure to do so risks patient lives, but stock-outs have occurred even when a manufacturer has "over-supplied" a market with many times the amount of drug expected to meet local demand. These stock-outs have occurred as a result of parallel trade. In these cases, as little as a 10% variance on pack cost is enough to trigger parallel trade, which can result from price variations at launch across the EU and currency fluctuations following launch. These situations form a useful series of case studies to determine supply chain issues leading to stock-outs. Based on this case study analysis, a model is being developed to estimate the degree of exposure to risk of parallel trade and its associated potential cost to the manufacturer/supplier, and to patient access. The model identifies and quantifies trade flow patterns and key elements. Consequently, supply planning is possible based on essential metrics identified in the trade flow patterns. An allocation scheme to meet local needs is the key output of the model. The allocation scheme is applied to limit stock to the country to be in line with demand, plus a smaller variance (depending on local conditions) for that market compared to that previously applied. The model is intended for use in key EU markets (France, Germany, Italy, The Netherlands, Spain, Italy, UK) as well as countries in Central and Eastern Europe. The model should help to optimise supply chain planning and operations, thereby minimising the risk of stock-outs. Consequently, all patients requiring specific, potentially life-saving drugs should have access to these treatments.

PHP289

SUSTAINABLE HEALTH CARE SYSTEMS: THE ROLE OF THERAPEUTIC VALUE AND VALUE BASED PRICING

Hulshof JAM
Simon-Kucher & Partners, Bonn, Germany

It is a common perception that the cost of pharmaceutical care, driven by the price of medicines, is a major contributor to increasing public health care expenditure, the culprit of unsustainability of health care systems. This presentation shows how the net effect of value-based pricing of new, innovative treatments and competitive pricing of older, often generic, products defeats that perception. The growth of pharmaceutical expenditure is, in fact, leveling off in most European countries, a trend that started even before the economic crisis of 2008. Value based pricing is an approach by which the pricing strategy is determined by therapeutic value, economic value and cost-effectiveness. Value based pricing requires a substantial body of sophisticated evidence, generated throughout product development. Competitive pricing is an approach by which the pricing strategy of older products is defined relative to the price of direct competitors in order to maximize market share. Competitive pricing occurs in crowded markets with multiple equal or undifferentiated treatment options. In recent years, competitive pricing has brought the price of many widely prescribed drugs significantly down. These two approaches to strategic pricing take place against the backdrop of tightening public financing rules that aim at ensuring financial sustainability of publicly financed health care systems. Consequence thereof is a two-tiered market access decision-making routine: for high-value/high-priced innovative treatments centralized decision-making based on value assessment with evidence, restricting them to a tightly characterized severely ill patient sub-population with low volume and/or a sales ceiling; versus local decision-making based on lowest (net) price for high-volume multisource products or equivalent single-source products, leading to significantly lower (net) prices than the originator at time of launch. Sustainable pharmaceutical care with openness towards innovation is therefore within reach.

PHP290

ECONOMIC EVALUATION IN PORTUGAL – ESTABLISHMENT OF THE NATIONAL HEALTH TECHNOLOGY ASSESSMENT SYSTEM (SINATS)

Cortegaça P, Silva F, Viana D, Ramos R, Martins J
INFARMED, I.P., Lisbon, Portugal

Economics is a social science that has a focus on allocating limited resources efficiently. In health care is essential to invest properly, assuring access to health technologies with the best cost-effective profile, ensuring the sustainability of National Health Systems. In Portugal, the INFARMED – National Authority of Medicines and Health Products I.P., has been making economic evaluations of medicines for 15 years, and is currently developing the National Health Technology Assessment System – SiNATS, of the utmost importance to the National Health System. Nowadays the assessment of the technologies (relative effectiveness assessment and cost-effectiveness) is focused on medicines, within the reimbursement process and the preliminary assessment to its acquisition by the National Health System's Hospitals. Consequently, it is always done before the reimbursement decision, as a supporting tool to the decision itself. The purpose of this model is to guarantee a global system, and at the same time, extending it to new technologies besides medicines, e.g. medical devices. In these cases, the cost-effectiveness evaluation will be done through the whole life-cycle of that technology, affecting its price and use considering its real performance; instead of only its market entry. The INFARMED, by developing SiNATS, intends to contribute to minimize expenditures in health and the citizens' life quality, in order to assure the National Health System's sustainability and efficient usage of public resources in health. Moreover, this system also aims to observe the technologies' effectiveness and its usage, with the purpose of reducing wastes as well as to promote and award innovation and equal access to health technologies. This research intends to verify the applicability of the universal key principles of Health Technology Assessment Systems in SiNATS, in order to guarantee that the model achieves its proposing objectives. The study will be focused on the structure of system.

PHP291

MARKET ACCESS AND REIMBURSEMENT OPTIONS FOR ORPHAN DURG HOSPITAL ONLY MEDICINES IN EUROPE – ONE SIZE FITS ALL?

Vosgerau S[1], Paulus G[1], Plantoer S[2]
[1]*IMS Health, Munich, Germany,* [2]*IMS HEALTH GmbH & Co. OHG, Munich, Germany*

Orphan drugs are medicines used to the treat life-threatening or chronic diseases affecting very rare diseases. From April 2000 to October 2010, 720 drugs received orphan drug designation from the European Medicines Agency (EMA). Hereof, 63 were granted marketing a marketing authorization. Since then - with an annual orphan drug sales volume of more than $6 billion - there has been a steady increase in applications for orphan designation with the Committee for Orphan Medicinal Products (COMP), averaging ten positive recommendations per month. Although central approval of orphan drugs covers 30 European countries, it does not necessarily provide for national availability as each national authority has to agree to market access and reimbursement. Further, the hospital sector is known for its high diversity in terms of national access mechanisms and degree of centralization, exemplified by the Nordic Countries: In Denmark and Norway a highly centralized hospital sector prevails with one main hospital procurement agency (AMGROS in Denmark and LIS in Norway), while in Sweden and Finland several county councils are authorized to make decisions independently from each other. The objective of the present study is to identify and evaluate possible short cut routes to market access and reimbursement for orphan drug hospital only medicines (OD-HOM) in EU and further investigate country specific requirements for identified short cut routes to market access and reimbursement for OD HOM in EU as strategic options. A literature review and further desk research was performed. The following countries are included in the analysis: Nordic Countries, Germany, France, The Netherlands and Spain. The results of the ongoing OD-HOM research will be displayed as a summary